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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/361,542	07/27/99	DOBROZSI	D 7247M

EXAMINER

HM22/0314

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ART UNIT	PAPER NUMBER
1615	3

DATE MAILED: 03/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *27 July 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statement, received October 18, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 9, 11, 24, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Chavkin et al. Chavkin et al disclose an oral, liquid composition for suspending orally administrable pharmaceutical active compositions comprising colloidal silicone dioxide (abstract), more specifically fumed silicone dioxide (col 3, line 68). Chavkin et al also teach that the pharmaceutical active can be selected from gastrointestinal agents, as well as mucosal bioadhesives (col 8, claim 10). Chavkin et al further teach that the colloidal silicone should be present at 2% by weight (col 4, example 1). This disclosure teaches the above mentioned claims because the claims are drawn to a composition, and Chavkin et al teaches the same components in the composition. Further, because Chavkin et al teaches the same components in the

composition, the ratios and viscosities claimed by applicant are considered inherent to the composition, absent any evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chavkin et al as applied to claims 1-6, 8, 9, 11, 24, and 28 above, and further in view of Ponchel et al. Chavkin et al disclose the components of the composition claimed by applicant. Chavkin et al do not teach that the formulation can be in a form for intranasal use. However, it is the position of the examiner that this application would have been obvious to one of ordinary skill in the art at the time the invention was made. Applicant claims a mucoretentive, aqueous suspension, and applicant teaches that the three main mucosal surfaces in the body are in the gastrointestinal tract, the nasal tract, and the vaginal cavity. Therefore it is the position of the examiner that once a mucoadhesive composition which comprises a pharmaceutical active is identified, it would be obvious to use the composition in whichever well known method would best deliver the active to the appropriate mucosal layer. The Ponchel et al reference is relied upon to teach "that the therapeutic potential of colloidal drug carriers after oral drug administration is ... to

increase bioavailability by protecting the drug from denaturation in the gastro-intestinal lumen, or by increasing the drug concentration for a prolonged period of time directly at the surface of the mucus membrane." (abstract)

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Pulliam, whose telephone number is (703) 308-4710. The examiner can normally be reached Monday to Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600